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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,601

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Dan Rico

2223-198

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1059 7590 06/30/2008

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EXAMINER

BITAR, NANCY

ART UNIT

PAPER NUMBER

2624

MAIL DATE

DELIVERY MODE

06/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,601	Applicant(s) RICO ET AL.	
	Examiner NANCY BITAR	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

1. Claims 5-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 5 defines a "computer program product

“embodying functional descriptive material. However, the claim does not define a computer-readable medium or memory and is thus non-statutory for that reason (i.e., “When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized” – Guidelines Annex IV). That is, the scope of the presently claimed “computer program product “can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to “computer-readable medium encoded with a computer program” or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure.

Examiner Notes

2. Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samani et al (Biomechanical 3-D Finite Element Modeling of the Human Breast Using MRI Data) in view of Brady et al (US 7,315,640).

As to claim 1, Samani et al teaches a method of generating a three-dimensional breast thickness object for a digital mammogram of a breast, the method comprising:

(a) generating a phantom thickness object for transforming into the breast thickness object (a cubic agarose phantom with cylindrical inclusion was constructed and imaged using MRI, page 272, 2nd L paragraph, figure 1b), the phantom thickness object being generated in a three-dimensional modeling means and being substantially breast-shaped (breast image nonrigid registration, paragraph III.B); (b) determining a set of dimensions for the breast (table 1, page 276, see figure 2, breast boundaries in the TI meshing technique); and (c) transforming the phantom thickness object to conform to the set of dimensions to provide the three-dimensional breast thickness object in the three-dimensional modeling means (based on the known geometry of the phantom a mesh was created, paragraph III, page 275-276). While Samani et al meets a number of the limitations of the claimed invention, as pointed out more fully above, Samani fails to specifically teach the set of dimensions of the breast to conform with the phantom thickness object. Specifically, Brady et al. teaches the use of a set of dimensions (see figures 20-21-22) in enhancing and normalizing x-ray images, particularly mammograms, by correcting the image for digitizer blur, glare from the intensifying screen and the anode-heel effect. The method also allows the calculation of the compressed thickness of the imaged breast and calculation of the

contribution to the mammograms of the extra focal radiation. The correction of the image for glare from the intensifying screen allows the detection of noise, such as film shot noise, in the image, and in particular the differentiation between such noise and. it would have been obvious to one of ordinary skill in the art to transform the phantom thickness object to conform to the set of dimensions in Samani et al. breast image in order to factor out the imaging parameters particular to the examination to yield an accurate representation of the intrinsic anatomy that is ultimately what is relevant for diagnosis. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 5, Samani et al teaches a computer program product for use on a computer system for analyzing digital mammograms, the computer program product comprising (a) a recording medium;(b) phantom thickness object generation means recorded on the recording medium for instructing the computer system to generate the phantom thickness object (breast image nonrigid registration, paragraph III.B);(c) data entry generation means recorded on the recording medium for instructing the computer system to upload a set of dimensions for the breast (see figure 2, breast boundaries in the TI meshing technique); and (d) transformation generation means recorded on the recording medium for instructing the computer system to transform the phantom thickness object to conform to the set of dimensions for the breast to provide the three-dimensional breast thickness object (based on the know geometry of the phantom a mesh was created, paragraph III, page 275-276).

As to claims 2 and 6, Samani et al. teaches the set of dimensions comprises a thickness readout for the breast and a size of the digital mammogram and wherein step (c) comprises normalizing a set of thickness values of the phantom thickness object based on the thickness

readout for the breast; and, rescaling the phantom thickness object to the size of the digital mammogram (pages 275-276, III. B, Breast Image nonrigid Registration; see also Brady et al., figure 17).

As to claims 3 and 7, Brady et al teaches a set of phantom landmarks at the edge of the phantom thickness object; determining a set of breast landmarks at the edge of the digital mammogram; and warping the phantom thickness object to map the set of phantom landmarks onto the set of breast landmarks. (Figure 18 and 19)

As to claims 4 and 8, Brady teaches the method as defined in claim 3 further comprising determining a second set of phantom landmarks on the phantom thickness object; estimating a breast density at a second set of points in the digital mammogram to determine a breast local thickness at the second set of point and a second set of breast landmarks corresponding to the second set of points; and warping the phantom thickness object to map the second set, of phantom landmarks onto the second set of breast landmarks (calculating from image densities of an x-ray film image the energy which was imparted to an intensifying screen used to receive x-rays and emit light to be recorded on the x-ray film, the apparatus comprising a processor controlled in accordance with a control program to fit a theoretical model of the expected response of the x-ray film and intensifying screen to a plurality of different intensities of received x-rays to a measured response, and to use the fitted theoretical model to calculate the imparted energy from image density, wherein the theoretical model is a serpentine curve of the form: $x \cdot \sup{.2}y + a \cdot \sup{.2}y - b \cdot \sup{.2}x = 0$, where a and b are constants, x is a logarithm of the energy imparted to the intensifying screen and y is the image density, see column 16, lines 35-33).

The limitation of claims 9-12 has been addressed above in claim 1-4.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on 571-272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew W. Johns/
Primary Examiner, Art Unit 2624

Nancy Bitar

05/30/2008